maxtec

SENSING. ANALYSIS. DELIVERY.

DECLARATION OF CONFORMITY

Manufacturer's Name:	Maxtec
Address:	2305 South 1070 West Salt Lake City, Utah 84119 USA
European Representative:	QNET BV Kantstraat 19 NL-5076 NP Haaren The Netherlands
Product:	MaxO2ME Oxygen Monitor
Model(s):	MaxO2ME (Including Pole Mount Bracket Accessories R100P10, R205P86, R206P75 and R206P76)
Classification & GMDN:	IIb Analyzer, Gas, Oxygen 35219
Classification criteria:	Clause 3.1 Rule 9 of Annex IX of MDD

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documents are retained under the premises of the manufacturer and the European Representative.

Directives:	General application directives: Medical Device Directive, COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 per Annex II as amended by 2007/47/EC of 5 September 2007
Notified Body:	TÜV SÜD Product Service RIDLERSTRASSE 65, D-80339 MUNICH, Germany Number 0123
EC Certificate No.:	G1 16 10 45041 020
Date CE mark was affixed:	5/14/16

This declaration is considered valid from May 2, 2019 to December 18, 2021

Signature: Tammy Lavery Date: 2 May 2019

Name: Tammy Lavery

Position: Director of Regulatory and Quality

Applied Standards

The referenced list of harmonized standards for which documented evidence of compliance can be provided includes:

ISO 80601-2-55:2011
EN ISO 14971:2012
IEC 60601-1:2005
IEC 60601-1-2:2014
CAN/CSA C22.2 NO. 60601-1:14
EN 62366:2008
EN 1041:2008
ISO 15223-1:2016
EN ISO 10993-1:2009
ISTA 2A
EN 50581:2012
IEC 60601-1-8:2006